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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/644,503	08/24/2000	John D. Kutzko	SMG200A1	3140

7590

05/03/2004

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EXAMINER

JARRETT, RYAN A

ART UNIT

PAPER NUMBER

2125

DATE MAILED: 05/03/2004

4

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/644,503

Applicant(s)

KUTZKO ET AL.

Examiner

Ryan A. Jarrett

Art Unit

2125

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 August 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-50 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 2.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 4-6, 9, 14, 23, 24, 26, 30, 38, 39, 41, and 45 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Referring to claims 4, 9, 14, 23, 26, 30, 38, 41, and 45, which represent the numerical surrogate markers embodiment of the invention, it is not clear where the limitation "the percent of individual patient response multiplied by a response factor" is enabled by the equation in the specification. In other words, in the numerical surrogate markers equation on page 6 of the Applicant's specification, it is unclear what term in the equation represents the "percent of individual patient response", and what term in the equation represents the "response factor".

Claims 5, 6, 24, and 39 depend from claims 4, 23, and 38 and therefore incorporate the same deficiencies.

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1-50 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15 of McMichael U.S. Patent No. 6,267,116. The claims of McMichael are directed to a method of calculating a revised dose of a drug for a patient, whereas the claims of the present application are directed to a method of calculating a revised dose of an anticoagulant, such as Coumadin® or warfarin. The method steps for both

Art Unit: 2125

sets of claims is the same, the only difference being that the claims of the present application specifically recite that the drug is an anticoagulant, such as Coumadin® or warfarin. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use an anticoagulant, such as Coumadin® or warfarin, in the method of McMichael. It would have been obvious to use any type of drug in the method of McMichael as long as the effect of the drug in the patient were capable of being measured using surrogate markers. It is well known that the effects of anticoagulants in a patient can be detected by measuring levels of surrogate markers in the patient's blood. Thus, there would have been a reasonable expectation of success that the use of anticoagulants, such as Coumadin® or warfarin, could be incorporated into the method of McMichael.

Claim Objections

5. Claims 5 and 18 objected to because of the following informalities: the limitation "D = DDNM – PDNM" should be changed to "D = DANM – PANM". Appropriate correction is required.

Conclusion

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ryan A. Jarrett whose telephone number is (703) 308-4739. The examiner can normally be reached on 10:00-6:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Leo Picard can be reached on (703) 308-0538. The fax

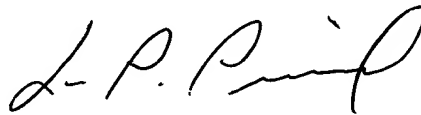
Art Unit: 2125

phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ryan A. Jarrett
Examiner
Art Unit 2125

4/29/04



LEO PICARD
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 2100